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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Subj: Docket No. 99D-5347 (Xenotransplantation)

To whom it may concern:

The proposed guideline to "indefinitely defer" blood donations from xenotransplantation recipients, their close contacts, and relevant hospital and laboratory personnel is inadequate and has no chance of protecting the U.S. blood supply as currently written.

Only a national computerized name-based registry, listing the names and addresses of patients and their close contacts would allow the identification of these individuals, to prevent them from donating blood.

Such a registry, however, is plagued by problems: it is unduly invasive of privacy and restrictive of liberty; its procedures cannot be legally enforced; it would be expensive to set up and manage; and will always be vulnerable to human error (such as if patients marry, change their names, relocate, or if hospital procedures are not carried out correctly.)

Moreover, the proposed guidelines ignore the fact that some viruses are latent. Like "mad cow disease," symptoms of disease from a pig virus, for example, may not manifest themselves for decades after infection, with devastating consequences for the blood supply.

When dealing with infectious diseases, a public policy based on containment is unacceptable. If it truly wanted to protect the blood supply and the public health, the FDA would ban xenotransplantation immediately.

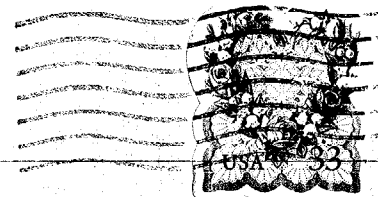
Sincerely,

Julie L Stamp
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99D-5347

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